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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/065,667	12/17/1999	LENNART CEDGARD	ALBHN-W-3.3	9154
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LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER AFREMOVA, VERA				
ART UNIT		PAPER NUMBER		
1651				

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,667

Applicant(s)

CEDGARD, LENNART

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11, 12, 14-27 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11, 12, 14-27 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2003 has been entered.

Status of claims

Claims 11, 12, 14-27 and 29-32 as amended 10/20/2003 are pending and under examination. Claims 1-10 were canceled by applicant in Preliminary amendment [paper No. 8 filed 2/05/2001]. Claim 13 was canceled by applicant [Paper No. 11 filed 5/21/2001]. Claim 28 was canceled by applicant [Paper No. 20 filed 8/07/2002].

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). However, it is uncertain whether the certified copy has been filed in parent Application No. 09/029,336. Please, provide evidence of filing or certified copy the foreign priority documents.

Specification

The disclosure is objected to because of the following informalities:

Please, insert in the first sentence of the specification updated information about continuing data and domestic priority based on 09/029,336. Appropriate correction is required.

Response to Arguments

Applicant's arguments filed 10/20/2003 with regard to claims rejection under 35 U.S.C. 112 have been fully considered and found persuasive as related to the pending claims as presently amended. Thus, claim rejections under 35 U.S.C. 112, *first and second paragraphs*, have been withdrawn.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 12, 14-27 and 29-32 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,396,631 taken with US 5,536,526; US 5,531,989; US 5,422,346; US 4,021, 545 and US 4,806,368

The claims are directed to a method for producing tablets with live bacteria comprising step of mixing live bacteria with fructose oligosaccharide or inulin and step of compressing the mixture into tablets. The final compressed tablet is characterized by good friability within 0.1-1.0 and by bacterial viability after compressing tablets of about 60%. Some claims are/are further drawn to the use of particular species of bacteria such as *Lactobacillus bulgaricus*, *Lactobacillus plantarum*, *Streptococcus thermophilus* or *Bifidobacterium animalis* in the method for producing tablets with live bacteria. Some claims are further drawn to the use of fructose oligosaccharide or inulin at concentration 40-99.5% in the tablet in the method for producing tablets with live bacteria. Some claims are further drawn to incorporation of additives into the tablet including starch or calcium diphosphate in the method for producing tablets with live bacteria.

US 4,396,631 teaches a method for producing hard tablets with live bacteria wherein the method comprises step of mixing live bacteria with binding materials and additives including starch, sugar, gelatin and others additives suitable for forming tablets and step of compressing the mixture in order to form tablets with viable bacteria. The cited patent clearly discloses that bacteria retain high viability (2×10^8 cfu) after formation of the compressed tablets as well as during storage of the compressed tablets (col. 4, example 1).

The cited patent US 4,396,631 is silent with regard to friability of tablets. However, it is well established in the art that compressed tablets have friability of about 0.3 according to good manufacturing practice as demonstrated by US 5,536,526 (col. 4, lines 7-10).

The cited patent US 4,396,631 is lacking the disclosure about the use of fructose oligosaccharide or inulin in the method for making hard tablets with live bacteria.

However, US 5,422,346 teaches the use of fructose oligosaccharide or inulin in the method for producing hard tablets and it also teaches that inulin is compressed into tablets without the need of additional binding materials such as starch, for example: col. 8, lines 41-44. The cited patent US 5,422,346 also teaches that inulin is a suitable substrate for promoting growth of beneficial bacteria such as lactic bacteria including *Bifidobacterium sp* and that the pathogenic enteric bacteria cannot utilize inulin, unlike the beneficial bacteria in the gastrointestinal tract of animals (col. 18, lines 25-37).

US 5,531,989 is relied upon to demonstrate a method for producing dry agglomerates with live lactic bacteria by using fructose oligosaccharide or inulin wherein the final products comprise about 40-60 % by weight of inulin and/or fructose oligosaccharide and about 0.1-20% by weight of live lactic bacteria of *Lactobacillus sp.* and/or *Bifidobacterium sp.* including *L. bulgaricus* and *L. plantarum* (col. 13, lines 38-50 and col. 4, lines 1-30). Although the cited patent US 5,531,989 is silent about hardness and/or friability of the final agglomerated products, it clearly teaches the use of live lactic bacteria in combination with inulin in the method of producing agglomerates wherein the final agglomerated products contain viable bacteria.

In addition, US 4,021, 545 is relied upon for the disclosure about the use of various materials including inulin, starch, calcium diphosphate and others in the methods for producing hard tablets (col. 5, example 4).

And US 4,806,368 is relied upon for the disclosure about the use of various materials including vitamins, cellulose or fibers in the methods for producing hard tablets (col. 5, example 4). The cited US 4,806,368 also teaches that hard tablets allow for prolonged storage of live bacteria containing tablets when compared to the dry agglomerated powders.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute inulin for starch or to add inulin into the tablets in the method for making hard tablets with viable bacteria in the method of US 4,396,631 with a reasonable expectation in success for producing hard tablets with viable bacteria because inulin has been taught as a substitution for the other binding agents including starch in the hard tablets {US 5,422,346; US 4,021,545} and because inulin has been demonstrated in the products with live bacteria {US 5,531,989} as adequately demonstrated by the cited prior art. One ordinary of skill in the art would have been motivated to incorporate inulin in the live bacteria-containing tablets for the expected gastrointestinal health benefits upon administration of these tablets because inulin is a beneficial substrate for promoting growth of beneficial probiotic bacteria including lactic bacteria and because inulin is not readily utilized by pathogenic enteric bacteria {US 5,422,346}. Thus, incorporation of inulin in the live-bacteria-containing tablets provides for the effects of the competitive exclusion of pathogenic bacteria by beneficial probiotic bacterial preparations {US 5,422,346; US 5,531,989}. One ordinary of skill in the art would also have been motivated to make hard tablets with live lactic bacteria because the hard tablets allow for

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preservation of the viability of live lactic bacteria for longer periods of storage unlike the dry bacterial powders as adequately taught by the prior art {US 4,806,368}. Accordingly, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351 till January 15, 2004 or (571) 271-0914 after January 15, 2004. The examiner can normally be reached on 9.30 am - 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743 till January 15, 2004 or on (571) 272-0926 after January 15, 2004.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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January 7, 2004.



VERA AFREMOVA

PATENT EXAMINER